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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,785	08/22/2003	Mark S. Vreeke	MSE #2658	8079

7590 12/21/2006

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1753	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,785	VREEKE ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 22 August 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/22/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6-22, and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Beaty et al. (WO 99/32881 A1) ("Beaty").

Addressing claim 1, Beaty discloses a method of determining glucose concentration in a whole blood sample (abstract) comprising;

providing an electrochemical sensor (31, 131) adapted to measure glucose and hematocrit concentration (abstract; page 07, lines 10-15; page 10, lines 25-32; page 06, line 30 – page 07, line 15; page 07, line 28 – page 08, line16; page 16, lines 20-30; page 17, lines 25-31; page 18, lines 01-09; and page 19, lines 06-16);

measuring the hematocrit concentration of the whole blood sample using the electrochemical sensor via electrochemical impedance spectroscopy (page 16, lines 20-30);

measuring the initial glucose concentration of the whole blood sample using the electrochemical sensor (page 11, lines 20-23 and page 15, line 28 – page 16, line 19); and

calculating the unbiased glucose concentration in the whole blood sample using the initial glucose concentration measurement and the hematocrit concentration (page 16, line 20 – page 17, line 31).

Addressing claim 2, for the additional limitation of this claim see in Beaty page 15, lines 21-23 and page 11, lines 20-24.

Addressing claim 3, for the additional limitation of this claim see in Beaty Figure 3; page 10, lines 10-13; and page 15, lines 21-27.

Addressing claims 6 and 19, for the additional limitation of this claim see in Beaty page 06, line 30 – page 07, line 15.

Addressing claim 7, the additional limitation of this claim is implied by page 05, lines 03-08, which discloses that the method is to be used to determine the concentration of a *medically* significant component of a *biological* fluid.

Addressing claim 8, the additional limitation of this claim is implied by page 18, lines 01-09, which discloses determining the various frequency responses of the sensor before determining the glucose concentration and that alternatively the glucose concentration can be determined before the concentration of the interferants.

Addressing claims 9 and 20, for the additional limitation of this claim see in Beaty page 09, lines 08-18.

Addressing claims 10 and 21, for the additional limitation of this claim see in Beaty page 19, lines 06-16, which discloses that a plurality of frequency measurements be performed to select the optimum one of measuring the hemaotocrit concentration. Note also page 16, lines 20-30, which discloses sweeping though a frequency range to determine several parameters of the sample.

Addressing claims 11 and 22, for the additional limitation of this claim see the bottom of page 14 in Beaty, which discloses calculating the phase of the strip impedance.

Addressing claim 12, for the additional limitation of this claim note that the claimed frequency range of about 800 and about 900 Hz falls within a disclosed range in Beaty of 10 Hz – 10 KHz. See page 16, lines 20-30.

Addressing claims 13 and 24, for the additional limitation of this claim see page 14, lines 04-14.

Addressing claims 14, 15, 25, and 26, for the additional limitation of this claim note Beaty discloses a frequency range of 10 Hz – 10 KHz. See page 16, lines 20-30.

Addressing claims 16 and 27, for the additional limitation of this claim see page 08, lines 18-22.

Addressing claims 17 and 28, for the additional limitation of this claim see page 17, lines 22-25.

Addressing claim 18, Beaty discloses a method of determining glucose concentration in a whole blood sample (abstract) comprising;

providing an electrochemical sensor (31, 131) adapted to measure glucose and hematocrit concentration (abstract; page 07, lines 10-15; page 10, lines 25-32; page 06, line 30 – page 07, line 15; page 07, line 28 – page 08, line16; page 16, lines 20-30; page 17, lines 25-31; page 18, lines 01-09; and page 19, lines 06-16);

measuring the hematocrit concentration of the whole blood sample using the electrochemical sensor via electrochemical impedance spectroscopy using an amperometric monitoring system (page 16, lines 20-30; page 09, line 19 – page 10, line 13);

measuring the initial glucose concentration of the whole blood sample using the electrochemical sensor (page 11, lines 20-23 and page 15, line 28 – page 16, line 19); and

calculating the unbiased glucose concentration in the whole blood sample using the initial glucose concentration measurement and the hematocrit concentration (page 16, line 20 – page 17, line 31).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beaty et al. (WO 99/32881 A1) ("Beaty") in view of Walling et al. (US 5,508,171), Diebold et al. (US 5,437,999), and White et al. (US 5,352,351).

Beaty discloses a method of determining glucose concentration in a whole blood sample (abstract) comprising;

providing an electrochemical sensor (31, 131) adapted to measure glucose and hematocrit concentration (abstract; page 07, lines 10-15; page 10, lines 25-32; page 06, line 30 – page 07, line 15; page 07, line 28 – page 08, line16; page 16, lines 20-30; page 17, lines 25-31; page 18, lines 01-09; and page 19, lines 06-16);

measuring the hematocrit concentration of the whole blood sample using the electrochemical sensor via electrochemical impedance spectroscopy (page 16, lines 20-30);

measuring the initial glucose concentration of the whole blood sample using the electrochemical sensor (page 11, lines 20-23 and page 15, line 28 – page 16, line 19); and

calculating the unbiased glucose concentration in the whole blood sample using the initial glucose concentration measurement and the hematocrit concentration (page 16, line 20 – page 17, line 31).

Beaty also discloses having the glucose concentration of the whole blood sample be determined using an amperometric monitoring system and having the electrochemical sensor include an insulating base plate, an electrode system on the base plate and a cover adapted to mate with the base plate to form a space in which the electrode layer is available to contact the whole blood sample. See in Beaty page 15, lines 21-23; page 11, lines 20-24; Figure 3; page 10, lines 10-13; and page 15, lines 21-27.

Beaty does not specifically mention including a reaction layer comprising an enzyme that reacts with glucose in the whole blood sample. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to do so because Beaty discloses providing in the sensor "a chemistry which reacts with the medically significant component" and a number (if not all) of the exemplary biosensor

with the which the method can be practiced include an enzyme in the reaction layer that reacts with glucose. See in Beaty page 5, lines 03-08 and page 08, lines 23-25; in US 5,508,171 Table 1, which spans columns 5 and 6; in US 5,437,999 Table 1 in column 10; and in US 5,352,351 column 05, lines 42-46.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beaty et al. (WO 99/32881 A1) ("Beaty"), Walling et al. (US 5,508,171), Diebold et al. (US 5,437,999), and White et al. (US 5,352,351 as applied to claim 4 above, and further in view of Pollmann et al. (US 5,288,636) ("Pollmann") and NATROSOL® product literature from Aqaulon ("Natrosol").

Beaty does not mention combining with the enzyme a hydrophilic polymer.

Pollman, which Beaty discloses is an exemplary biosensor with the which the method can be practiced includes the hydrophilic polymer NATROSOL® with enzyme in the reaction layer. See in Beaty page 5, lines 03-08 and page 08, lines 23-25; in Pollmann col. 07:07-31; and Natrosol, first sentence.

It would have been obvious to one with ordinary skill in the art at the time of the invention to combine the enzyme with a hydrophilic polymer as taught by Pollmann in the invention of Beaty because as taught by Pollmann NATROSOL® will disperse the disperse the redox mediator in the reagent. See col. 06:67 – col. 07:09.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beaty et al. (WO 99/32881 A1) ("Beaty"),

Beaty discloses a method of determining glucose concentration in a whole blood sample (abstract) comprising;

providing an electrochemical sensor (31, 131) adapted to measure glucose and hematocrit concentration (abstract; page 07, lines 10-15; page 10, lines 25-32; page 06, line 30 – page 07, line 15; page 07, line 28 – page 08, line16; page 16, lines 20-30; page 17, lines 25-31; page 18, lines 01-09; and page 19, lines 06-16);

measuring the hematocrit concentration of the whole blood sample using the electrochemical sensor via electrochemical impedance spectroscopy using an amperometric monitoring system (page 16, lines 20-30; page 09, line 19 – page 10, line 13);

measuring the initial glucose concentration of the whole blood sample using the electrochemical sensor (page 11, lines 20-23 and page 15, line 28 – page 16, line 19); and

calculating the unbiased glucose concentration in the whole blood sample using the initial glucose concentration measurement and the hematocrit concentration (page 16, line 20 – page 17, line 31).

Beaty also discloses detecting the glucose concentration in whole blood in a disposable self-testing system, and performing a phase shift of an impedance measurement. see in Beaty page 06, line 30 – page 07, line 15 and the bottom of page 14 in Beaty, which discloses calculating the phase of the strip impedance.

Although Beaty does not mention measuring the hematocrit concentration with at least one frequency between 800 and about 900 Hz, Beaty does disclose a range of 10 Hz – 10 KHz, which includes the claimed range. Barring evidence to the contrary, such as unexpected results, using at least one frequency between 800 and about 900 Hz is just a matter of optimizing the frequency because as taught by Beaty, "It is not possible to predict, for example, in what frequency range hematocrit's concentration will be optimally uncoupled from uric acid's or bilirubin's without reference to the specific physical and chemical characteristics of that cell. Some investigation will be required to determine these optimum frequency ranges. However, the investigation will be relatively routine once the physical and chemical characteristics of the cell are known." See page 19, lines 06-16.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
December 18, 2006